
Issue 1 – Testing requirements

Stakeholders raised concerns regarding the import testing requirements, including:

- Requirements for bluetongue virus (BTV), bovine tuberculosis (BTB), infectious bovine rhinotracheitis (IBR) and bovine viral diarrhoea (BVD2) were believed to be onerous and overly restrictive. Modifications were requested for both live zoo bovids and semen.
- Disagreement with the assessment of risk for certain diseases in the draft review, particularly those diseases listed above.
- Concerns over animal and staff welfare and safety due to the need for repeated restraining events for testing.
- Requirements for herd or premises freedom in zoos would not be appropriate. Alternatives were requested.
- Queries were raised about changes made to the import requirements from a previous draft, without sufficient justification.

These issues were raised by Perth Zoo, Zoos Victoria, Taronga Conservation Society Australia and the Zoo and Aquarium Association (ZAA)

Response

The department understands concerns made from stakeholders and provided the following response:

- Import testing requirements have been developed by the department as part of the risk mitigation strategy to meet Australia's appropriate level of protection (ALOP) in accordance with Australia's *Biosecurity Act 2015*.
- When developing import requirements to manage biosecurity risk, the department considered a multitude of factors, including animal welfare and safety. These measures are designed to manage biosecurity risk consistent with Australia's ALOP while not being unnecessarily trade restrictive.
 - The department is willing to consider alternative risk mitigation strategies on a case by case basis, however alternative measures will only be accepted if Australia's ALOP can be met.
- Preliminary/early drafts of the risk review had been supplied to an industry body as a courtesy prior to any consultation, quality control, revision or assessment. Changes occurred as a result of that process.
- Concerns over disease specific testing requirements have been addressed in responses below.

Issue 2 – Testing of archived semen

Stakeholders raised the following concerns about requirements for the import of archived semen.

- Specifically, the ability to test donors of semen which is archived. Requirements for pre- and post- collection disease testing of donors will likely not be met for semen which is already archived. Request to add PCR testing of archived semen for BTV, BTB and Brucella.

Response

The department acknowledges the value in accessing archived semen for the Australian zoo industry. Approved tests have been developed for diseases such as IBR and BVDV as they have sufficient evidence of reliability however in other cases testing of semen may not adequately manage the biosecurity risk. There is insufficient evidence that PCR testing of semen would reliably detect organisms other than IBR and BVDV. These cases require additional measures such as donor testing consistent with the OIE code which considers semen testing an

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- Clarification was requested on requirements for testing of semen (single straw testing in a collection/ejaculate versus all straws).

Raised by Perth Zoo, Zoos Victoria and ZAA

adequate risk mitigation measure for IBR, but not BTV, BTB and Brucella.

In cases where testing of semen is allowed, a sample from every ejaculate must be tested. This information will be clarified in the review document.

Issue 3 – Testing of fresh and frozen semen

Stakeholders requested clarification on whether both fresh and frozen semen can be imported under the conditions in the draft review as it is not explicitly stated. The following issues were specifically highlighted:

- The requirements for the timing of post- collection testing make importation of fresh semen not possible as semen will need to be frozen to keep viable. Stakeholders request that review document make it clear that only frozen semen can be imported.

Raised by Perth Zoo, Zoos Victoria and ZAA

Response

The department considers both fresh and frozen semen eligible for export to Australia provided the import conditions have been met. The requirement for donors to be tested following semen collection is necessary to ensure Australia is protected from diseases of biosecurity concern. The department notes that restricting imports to frozen semen only would unnecessarily prevent trade in fresh semen should advances in technology make it possible in the future, and so will not include this requirement in the review.

Issue 4 – Semen extenders

Stakeholders requested clarification on the use of semen extenders.

Raised by Perth Zoo, Zoos Victoria, Taronga Conservation Society Australia and ZAA

Response

The department has updated the review to include the details of the relevant OIE Code Chapter (4.7.7) which lists the requirements and considerations for semen extenders for use in international trade.

Issue 5 – Infectious bovine rhinotracheitis (IBR/BoHV1)

Stakeholders raised issues with the risk review chapter for infectious bovine rhinotracheitis (IBR/BoHV1), including the following:

- Concerns the risk IBR in zoo bovids has been overstated in the draft review due to reliance on information from primary sources on non-zoo bovid species.
- Request that risk management is only applied to more virulent subtypes which are not present in Australia.

Response

The department considered the information provided by stakeholders on the entry of BoHV1 in association with zoo bovid importation and re-assessed the risk associated with infectious bovine rhinotracheitis. The department's position remains unchanged following this process as the risk associated with IBR was determined to exceed Australia's ALOP, therefore risk mitigation measures are required. The following was noted:

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- Stakeholders requested to have an option for animals continuously resident since birth on properties/premises where BoHV-1 has never been diagnosed.
 - Concerns about the likelihood of zoos undertaking herd testing.
 - Concerns about evidence that species covered by the draft review play a significant role in IBR epidemiology.
 - Stakeholders requested an option of country freedom is added as a possible risk management option for IBR.
 - Disagreement that any risk management should be required for IBR.

These issues were raised by Taronga Conservation Society Australia and ZAA

- The consequences of entry of more virulent strains of IBR into Australia include negative impacts on Australia's international trading position for live animals and meat products.
 - There is limited information on some diseases in zoo bovid species. Where this is the case literature from related studies, domestic livestock and general disease principles are considered to inform judgement of the biosecurity risks.
 - An absence of evidence of IBR in specific species cannot be interpreted as absence of BoHV1 in imports of all zoo bovinds. In addition, some zoo bovinds may not show clinical signs of infection with IBR and therefore sourcing from premises free of reports of this disease (without additional mitigation measures in place) would not adequately manage the biosecurity risk.
 - Due to lack of clinical signs in zoo bovinds, annual screening was considered appropriate to provide assurance on IBR status of the herd. The department is willing to consider alternative risk mitigation measures on a case by case basis.
 - The alternative import conditions suggested for IBR (including property of origin freedom only, single herd tests, or single testing of animals) were not considered to provide adequate risk mitigation.
 - Current molecular diagnostics (i.e. PCR or equivalent) are the only reliable means of differentiating between BoHV sub-types. The department is willing to consider applications for import where freedom from specific sub-types is demonstrated by molecular testing.
 - After due consideration, the department determined that a country freedom clause could, in certain circumstances, adequately manage the biosecurity risk. The import conditions have been revised to include this risk mitigation option where it can be demonstrated to the satisfaction of the department.
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Issue 6 – Bovine viral diarrhoea virus (BVDV/pestivirus)

The following issues with the risk review of bovine viral diarrhoea virus (BVDV) were raised by multiple stakeholders:

- Concerns that information on BVDV is being conflated between zoo bovid species covered by review and other species and that the risk was overstated.
- A lack of evidence for the role zoo bovids play in BVDV epidemiology,
- Risk management should only be in place for BVD type 2 as BVD type 1 is present in Australia.
- It would be unlikely that annual herd testing takes place in zoo/wildlife facility. Stakeholders requested removal of that option and replacement by measures they believe are more appropriate and applicable.
- Due to housing arrangements in Australian zoos, stakeholders expressed the belief that zoo bovids present very little risk to domestic cattle and there is no demonstrated pathway for transmission from zoo bovids to domestic cattle in Australia.
- A request that a list of countries free from BVD be made available.
- A request to allow an option for country freedom from BVD2 specifically.
- Differences in import requirements set by this review and those set in the 2010 IRA for Zoo bovids from New Zealand, which did not include risk management measures for pestivirus.
- A request for an alternative pre-export testing protocol to be added as an import requirement.

These issues were raised by Taronga Conservation Society Australia and ZAA

Response

The department considered the submissions by stakeholders and assessed that BVD type 2 presents a low level of biosecurity risk and therefore risk mitigation measures are warranted. The following was noted:

- The department must consider the consequences of importing BVD type 2 into Australia, which is not limited to the effect on zoos and could negatively impact on domestic animal health and international trade. The department notes that some Australian zoos hold domestic cattle and there are no restrictions on movement of zoo bovids after being imported into Australia, giving rise for potential transmission of BVD2 from zoo bovids to cattle.
- In addition, the Australian zoo industry is comprised of a variety of different animal holdings, with their own health programs and levels of biosecurity which vary. The department's import conditions consider and mitigate the risk associated with import into all types of zoo facilities.
- In accordance with normal practice for species where a limited amount of literature exists, the risk assessment considered literature on BVD type 2 in related species. The absence of clinical signs of BVD type 2 in some species does not demonstrate absence of infection, particularly where active disease surveillance is not performed.
- The department agrees freedom from BVD type 2 provides acceptable risk mitigation, provided testing that is performed can accurately distinguish between genotypes. The risk review has been amended to reflect this.
- As clinical signs are not pathognomonic for BVD, herd screening is required to demonstrate herd freedom. The department is willing to consider alternative risk mitigation measures to provide equivalent biosecurity outcomes on a case by case basis.

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- The department is willing to assess an exporting country's freedom from BVD2 on a case by case basis. An addendum has been added to the risk review to reflect this.
 - The department notes that the measures in the 2010 review, *Importation of zoo bovids from New Zealand*, was designed to manage the biosecurity risk of BVD2 in imports specifically from New Zealand, and not other countries.
 - The department does not consider the alternative pre-export single test protocol proposed by a stakeholder as being capable of managing the biosecurity risk to achieve Australia's ALOP.
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Issue 7 – Bluetongue virus (BTV)

Stakeholders raised a number of concerns with regards to the bluetongue virus chapter, including:

- A request to allow vaccination with a killed vaccine (for serotypes not present in Australia) as a risk mitigation option for live zoo bovids.
- A request for clarification of vector protection requirements.
- Concerns that the requirement for testing within 7 days of export would be onerous and require an animal restraint event, without a clear basis. Stakeholders requested this requirement be removed or the timing altered to coincide with testing for other diseases.
- Recognition of seasonal freedom from BTV is unclear in the draft and inconsistent with import conditions for cattle semen. Stakeholders requested an alternative approach to seasonal freedom for BTV.
- A request to allow import into a recognised *Culicoides* spp. free zone as a risk mitigation option.
- Stakeholders requested PCR testing of semen be included as an option that would allow importation of archived samples.

Response

The department considered information provided by the submissions and has revised the import measures to reduce the risk of BTV in zoo bovids to a level consistent with Australia's ALOP. The following responses were provided:

- The department does not consider vaccination as capable of providing acceptable risk mitigation for BTV due to limitations in cross-protection between serotypes, and a lack of assays available to differentiate between infected and vaccinated animals. Vaccination may also affect export market access.
 - The details of vector protection requirements are at the discretion of the exporting facility and will be assessed by the department at the time of import permit application, to allow flexibility. However, the department expects that physical vector protection of the facility would be included in the management plan, consistent with requirements in the Terrestrial Animal Health Code published by the OIE (Chapter 8.3.13).
 - Import requirements have been amended to require all animals arriving from countries/zones not free from BTV be imported into Australia's BTV transmission-free zone.
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These issues were raised by Taronga Conservations Society Australia and ZAA

Transmission of BTV between zoo bovids and domestic cattle is considered possible, particularly where vectors are present and zoos may be in close proximity to domestic cattle/buffalo.

- The department also notes the identified edge of the bluetongue zone of transmission may shift large distances rapidly to incorporate areas previously not considered at risk, and which may affect premises where zoo bovids undergo post-arrival quarantine.
- In addition, and consistent with OIE Code recommendations for BTV, zoo bovids will need to be housed in vector protected establishment from 14 days prior to pre-export blood sampling until time of export.
- The timing of pre-export blood sampling has been extended up to 14 days prior to export. This change gives greater flexibility in the timing of pre-export blood testing, as requested by stakeholders, which may also allow sampling for multiple disease protocols to be combined and require less restraint events over all.
- Seasonal freedom from BTV is assessed by the department. Acceptance of BTV seasonality for bovine semen from the US was based on risk assessment conducted at that time and is part of a suite of risk mitigation measures applied in such circumstances. The zoo bovids review reflects the latest assessments by the department for areas free or seasonally free from BTV, and the list may be updated in the future should circumstances change.
- In assessing the level of risk the department considers the consequences of entry, establishment and spread of a disease for all of Australia, including negative impacts on domestic production and Australia's international trading position for animals and meat products.

Issue 8 – Bovine tuberculosis (BTB)

Response

Stakeholders raised the following issues regarding the bovine tuberculosis chapter in the draft risk review:

- A request was made to add additional risk management options for animals which have been resident on premises where BTB has never been diagnosed.
- Clarification was requested regarding requirements of premises freedom for 5 years (no herd testing) or 3 years (with annual herd testing). A suggested alternative threshold of 15 to 20 years of BTB freedom on premises with less stringent pre-export testing requirements was provided.
- Concerns that no zoos undertake or would implement annual herd testing for TB, and therefore the measure is unnecessary. However, stakeholders were still open to options that include defined herd testing procedures for risk mitigation.
- A query whether animals must be in a pre-export quarantine (PEQ) facility during the 72-210 days pre-export testing window.
- Concerns that risk management measures were unnecessarily restrictive, place animal welfare at risk and have changed significantly from the previous draft where sequential testing requires repeated restraints poses a risk for animal welfare.
- A request for blood tests to be included as a risk mitigation option instead of sequential skin testing.
- A stakeholder noted that the requirements in this draft review are more onerous than those currently in place for the importation of zoo bovids from New Zealand, or for cattle semen. Requested similar conditions be used for live animals and semen.
- Stakeholders requested inclusion of country freedom as a risk mitigation measure.

These issues were raised by Taronga Conservations Society Australia and ZAA

The department has considered the submissions made by stakeholders and provided the following responses:

- There have been numerous reports of tuberculosis outbreaks in zoological facilities historically. The 3 year and 5 year requirements for premises freedom are considered to be the minimum periods of time required to provide adequate assurance of premises freedom.
- Herd testing requirements are defined in section 4.4.5 of the review. and provide the minimum conditions under which a screening program would provide adequate risk mitigation for BTB.
- Animals are not required to be in PEQ for testing performed between 72-210 days prior to export, however testing requirements within 30 prior to export will be carried out in pre-export isolation.
- An additional risk management option has been included that allows two of the three tests for BTB to be performed prior to entry into PEQ. In line with stakeholder comments, this may assist with management of animal welfare.
- The department notes the limitations of antemortem TB testing, particularly the sensitivity of such tests. Multiple tests are therefore required to reduce the risk of BTB to an acceptable level.
- Serological assays for BTB lack sensitivity when compared to tests of cell mediated immunity. The department is willing to consider alternative tests with appropriate levels of reliability if they become available in the future.
- Differences in risk mitigation measures between the 2010 review *Importation of zoo bovids from New Zealand* and the 2019 review *Importation of zoo bovids from approved countries* are required to account for the change in risk associated with a country specific policy (where measures such as specific

control programs in the country of export may be considered), to a generic policy.

- In many instances semen import conditions may not be applicable or may not provide adequate risk mitigation for live animals. This is because the level of risk of a disease can differ between the two commodities and risk management suitable for one commodity may not be transferable.

Issue 9 – Brucella

A stakeholder raised issues regarding the chapter on Brucella in the zoo bovid risk review. The following concerns were raised:

- The risk management options in the draft review for zoo bovids are more restrictive than those currently in place for domestic cattle semen from the US, without apparent increased risk.
- Lack of a demonstrated risk pathway for susceptible animals to transmit the disease to zoo bovids within the scope of the draft review.
- A reference to OIE manual did not contain the relevant information.
- A request that PCR testing of semen be used as a risk management option.

These issues were raised by ZAA

Response

The department considered the submissions by the stakeholder and provided the following responses:

- There are several considerations which result in differences between the draft zoo bovids review and the current bovine germplasm import policy.
- The current bovine germplasm import policy was released in 2006 whereas the draft import policy for zoo bovids considers more recent information of relevance to risk and risk management.
- Consideration was also given to practices and standards in the relevant industry sectors.
- Policies for specific countries often include more detailed evaluation of animal health status and veterinary services of that country.
- The reference to the OIE manual has been replaced with a reference which contains the appropriate information
- PCR testing as a risk management option is discussed in response to Issue 2 (above). There is insufficient evidence that PCR testing of semen would reliably detect Brucella. In addition, the OIE code does not consider semen testing an adequate risk mitigation measure for Brucella.

Issue 10 – Heartwater

Response

A stakeholder raised issues regarding the tick management requirements in the Heartwater chapter of the draft zoo bovid review. The following was noted in their submissions:

- The residency and country freedom requirements are longer than the carrier period (12 months) of infected animals.
- Specific tick management for heartwater differs from the general tick management requirements in the review. Suggest aligning tick management requirements between chapters for consistency.

These issues were raised by ZAA

The department considered the submission from stakeholders and provided the following explanation for the tick treatment requirements:

- The potential for infection to persist in a herd may be longer than the carrier period as disease may be maintained in a population of ticks.
- The specific conditions for tick management are in place to minimise the risk of tick reinfestation after treatment.

Issue 11 – Registered Zoos

Stakeholders raised issues with the requirement that animals must be from an approved licenced or registered zoo or wildlife park. Some genetically important or endangered zoo bovid species are held in private organisations and are not on public display. These organisations may not be registered and stakeholders request that conditions be put in place to import zoo bovid from non-registered zoos/organisations.

These issues were raised by the Taronga Conservation Society Australia and ZAA

Response

The department considered submissions by stakeholders regarding registered zoos. The generic import risk analysis was limited to establishments registered with the competent authority of the country of export to help achieve Australia’s ALOP, as the use of registered zoos provides assurance of the disease status of the premises and the source and health status of animals. If the scope of the review was expanded to non-registered/approved premises, then additional import conditions may need to be added to reliably achieve Australia’s ALOP.

- If an unregistered facility can demonstrate the ability to provide a comparable level of risk mitigation, the department may undertake an equivalence assessment.

Issue 12 – Pre-export quarantine standard operating procedures

Stakeholders requested a template be made available for standard operating procedures (SOPs) that would meet the department’s requirements for a pre-export quarantine facility (PEQ).

These concerns were raised by Taronga Conservation Society Australia and ZAA

Response

The department has developed documents to assist the zoo industry with the production of PEQ SOPs.

Issue 13 – Quarantine restriction

A stakeholder was unclear on the on the reference to quarantine restriction in *'The animal was not under quarantine restriction for the collection period or the 90 days immediately prior'* under semen testing.

This issue was raised by Taronga Conservation Society Australia.

Response

The department provided the following clarification: Quarantine restriction refers to the isolation of an animal or population of animals to prevent the spread of a controlled/notifiable disease. This term is commonly used among, and understood by, Australia's trading partners. Clarification can be provided directly if required.

Issue 14 – Equivalence

Stakeholders raised concerns about an over-reliance on equivalency assessments for disease risk management in cases where potential exporting zoos are unable to meet the conditions in the draft review

This issue was raised by ZAA

Response

The department considered the submissions regarding equivalence and provided the following response:

- While there may be a number of different scenarios for zoo bovid export, the scope of the risk analysis is restricted to the most common expected situations. An increase in the scope would delay the completion of the risk review and likely require more onerous import conditions.
- The import conditions currently in the review are considered appropriate to reliably achieve Australia's ALOP. Equivalence assessment provides a means where alternative measures proposed to achieve risk management to that same level will be considered by the department. This allows for unique circumstances, new technologies becoming available, and is compliant with Australia's international obligations.